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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,002	10/24/2003	Mike West	DU-P02-002	2470

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ROPES & GRAY LLP
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EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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09/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,002	WEST ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 18-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 19-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 18 and the original claims are related to newly submitted claims 20-23 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. According to the specification on page 3, the produce may be used to predict other outcomes besides those associated with breast cancer. For example, the model may be used to predict central nervous system embryonal tumor outcomes, or classification of human lung carcinomas, or lymphoblastic leukemia predictions (page 3 and 4 of the Specification). Each of these possible uses are drawn to a different disease and require a materially different process of using the model claimed in claim 18 and the original claims. Thus, claim 18 and the original claims are distinct from newly submitted claims 20-23 as a product and process of use.

Claim 18 and the original claims are related to newly submitted claim 19 as related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are

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mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different design, mode of operation, function and effect. Claim 18 and the original claims are drawn to a model. In contrast, newly submitted claim 19 is drawn to a computer readable medium that contains programs codes for conducting the process of predicting lymph nodes. Thus, claim 19 has materially different design, mode of operation, function, and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the Claims

Claims 1-17 are cancelled.

Claim 18 is under examination.

Claims 19-23 are withdrawn as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claim is drawn to the mathematical model of a classification tree. However, a classification tree is a form of data. Data does not fall within any of the statutory classes of a process, machine, manufacture, or composition of matter in 35 U.S.C. 101. Thus the instant claim is non-statutory.

This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buntine (Statistics and Computing (1992) Volume 2, pages 63-73) in view of Veer et al. (Nature (January 2002) Volume 415, pages 530-536).

The instant claim is drawn to a classification tree model incorporating Bayesian analysis where the tree model comprises one or more nodes representing metagenes (i.e., expression patterns of a set of genes) predictive of lymph node metastasis and one or more nodes representing risk factors.

Buntine teaches a general classification tree model with Bayesian analysis for the statistical prediction of binary outcomes (abstract; page 63) where binary outcome is a clinical state, physiological state, a physical state, disease state, or a risk group (page 63, right column; Figure 1); where the data is biological data (page 63, right column; Figure 1; page 66, left column 2nd full paragraph from the bottom).

However, Buntine does not teach where the tree model has one or more nodes representing metagenes predictive of lymph node metastasis.

Veer et al. teaches using data representing metagenes (the expression patterns of a set of genes) predictive of lymph node metastasis in a classification scheme to predict clinical outcomes (pages 531-533).

Buntine teaches a generic method of generating a classification tree model with Bayesian analysis. According to Buntine, his method may be used for a variety of different types of data, including biological data. Veer et al. teaches that using metagene expression pattern data improves the prediction of clinical outcomes of breast cancer.

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One of ordinary skill in the art would have used the metagene expression pattern data as the biological data in Buntine's classification tree model. Thus, the claim would have been obvious because the substitution of one known element for another would have yield predictable results to one of ordinary skill in the art at the time of the invention.

This rejection is necessitated by amendment.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561.

The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.
PRIMARY EXAMINER